DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 28, 2015

Ceramay GmbH & Co. KG
C/O Ms. Pamela Papineau, RAC
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K141400
Trade/Device Name: DCceram System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: October 30, 2014
Received: October 31, 2014

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141400

Device Name
DCceram System

Indications for Use *(Describe)*
The DCceram System is used to fabricate prostheses for missing/damaged teeth. The DCceram pressable ceramic ingots are pressed onto metal alloy (DCceram 12.5) or zirconia (DCceram 9.2) frames by dental technicians to fabricate ceramic restorations. DCceram 12.5 and DCceram 9.2 ceramic layering porcelains and shades are used to layer or build up the pressed ceramic to final tooth morphology and shade on the particular framework (DCceram 9.2 zirconia substructures; Dcceram 12.5 metal substructures). The DCceram conceptPress ceramic ingots are used to fabricate all-ceramic restorations. DCceram conceptArt ceramic stains and shades may be used with DCceram conceptPress or DCceram 9.2 ceramics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 4: 510(k) Summary (revised)

General Information

Date Prepared: July 8, 2014

Owner's Name: Ceramay GmbH & Co. KG
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Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
Telephone Number: (978) 772-3552
Fax Number: (978) 796-5460

Subject Device:
Trade Name: DCceram System
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II

Predicate Devices:
Product Name: In-Sync Ceramic System (Jensen Industries)
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II
Premarket Notification: K111743

Product Name: Willi Geller Creation CP L&M Porcelain (Jensen Industrties)
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II
Premarket Notification: K002904

Product Name: OPC 3G All-Ceramic System (Jeneric/Pentron)
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II
Premarket Notification: K994435

Indications for Use
The DCceram System is used to fabricate prostheses for missing/damaged teeth. The DCceram pressable ceramic ingots are pressed onto metal alloy (DCceram 12.5) or zirconia (DCceram 9.2) frames by dental technicians to fabricate ceramic restorations. DCceram 12.5 and DCceram 9.2 ceramic layering porcelains and shades are used to layer or build up the pressed ceramic to final tooth morphology and shade on the particular framework (DCceram 9.2 zirconia substructures; Dcceram 12.5 metal substructures). The DCceram conceptPress ceramic ingots are used to fabricate all-ceramic restorations. DCceram conceptArt ceramic stains and shades may be used with DCceram conceptPress or DCceram 9.2 ceramics.

Device Description
The DCceram System consists of several silica glass ceramic materials used to create ceramic and/or metal-ceramic dental prosthetic dental restorations, including inlays, onlays, veneers, crowns and bridges. The DCceram System components are available in a wide range of tooth shades (A1 – D4) as well as special shades. All DCceram System materials meet the physical properties requirements defined in ISO 6872:2008 *Dentistry – Ceramic Materials*, and are biocompatible as defined in ISO 7405:2008 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*.

The DCceram System components are:
- DCceram 9.2 & 12.5 pressable porcelain ingots
- DCceram conceptPress porcelain ingots
- DCceram9.2 liner/layering porcelain
- DCceram 12.5 liner/layering porcelain
- DCceram12.5 stains and shades
- DCceram conceptArt stains, shades and glazes

The DCceram9.2 and 12.5 ingots are silicate glass-based ceramic materials designed to create dental restorations using a lost wax technique in a vacuum press. DCceram 9.2 ingots are used with zirconia frameworks; DCceram 12.5 is compatible with metal (dental alloy) frameworks. The DCceram conceptPress ingots are used to create all-ceramic dental restorations. The complete DCceram System also includes a full line of compatible liner, build-up, layering and veneering ceramics. All system materials are available in a range of tooth shades.

Substantial Equivalence
The DCceram System is substantially equivalent to the Jensen Dental InSync Ceramic System (K111743), which is comprised of a full range of pressable, silica-based ceramic pellets and compatible layering porcelains used with zirconia and metal alloy frameworks, the Willi Geller CP L&M Porcelain (K002904), which is used with metal alloy frameworks, and to the Jeneric/Pentron OPC 3G All-Ceramic System (K994435), which includes pressable silica-based pellets and compatible layering porcelains used to create all-ceramic restorations. Substantial equivalence is based on indications for use, technological characteristics, material composition, usage techniques and conformity with consensus standards.

Testing
This 510(k) includes the results of performance testing to support compliance with ISO 6872:2008; these tests included coefficient of thermal expansion, transformation temperature, bending strength, chemical solubility and radioactivity for the DCceram System materials that are considered Type I or Type II, Class 1a materials per ISO 6872:2008. The DCceram conceptPress porcelain ingots are a Type II, Class 4b material per ISO 6872; testing for this system component consisted of coefficient of thermal expansion, transformation temperature,

bending strength, Weibull strength/modulus, fracture toughness, Martens hardness, chemical solubility and radioactivity. All DCceram System components met the minimum performance testing requirements specified in ISO 6872; where applicable (CTE, transformation temperature) the performance testing data has been incorporated into the device labelling.

The DCceram System materials were evaluated for biocompatibility in accordance with ISO 7405 and ISO 10993-5. This 510(k) includes the results of ISO 10993-5 cytotoxicity testing, which demonstrated that the DCceram System components are non-cytotoxic.

Conclusion

The DCceram System has been demonstrated to be substantially equivalent to the predicate devices.